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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DEANNA L. KROETZ, DARRYL C. ZELDIN,
BRUCE D. HAMMOCK, and CHRISTOPHE MORISSEAU

Appeal 2009-012055
Application 10/694,641
Technology Center 1600

Decided: June 22, 2010

Before ERIC GRIMES, DEMETRA J. MILLS, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

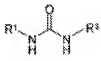
This is an appeal under 35 U.S.C. § 134 involving claims to a method of treating high blood pressure, which the Examiner has rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification discloses that soluble epoxide hydrolase (sEH) catalyzes the conversion of certain eicosanoids with vasodilatory properties to less active diols (Spec. 2: 1-24). The Specification discloses "methods of treating hypertension by administering to a patient a therapeutically effective amount of an inhibitor of epoxide hydrolase" (*id.* at 2: 28-29).

Claims 46 and 48 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 48 is representative and reads as follows:

> 48. A method of reducing hypertension in a patient, the method comprising administering to the patient a therapeutically effective amount of an inhibitor of soluble epoxide hydrolase, wherein said inhibitor or a pharmaceutically acceptable salt thereof is a compound having a structure of:



> wherein R^1 and R^3 are each independently selected from the group consisting of C_1-C_{20} substituted or unsubstituted alkyl, cycloalkyl, aryl, acyl, and heterocyclic.

Issue

The Examiner has rejected claims 46 and 48 under 35 U.S.C. § 102(e) as anticipated by Blum.[1] The Examiner finds that Blum discloses compounds encompassed by the formula of claim 48 and use of the compounds to treat hypertension (Ans. 4-5), in dosages that overlap those disclosed in the present Specification (*id.* at 6-7), "for the same ultimate

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[1] Blum et al., U.S. Patent 5,962,455, issued Oct. 5, 1999.

purpose (e.g., the treatment of hypertension) as disclosed by the applicant" and therefore Blum anticipates the claimed method (*id.* at 7).

Appellants contend that "the Examiner has not provided evidence or scientific reasoning to show that any compound of Blum inhibits sEH at all, much less sufficiently to reduce hypertension" (Appeal Br. 17). Appellants contend that they have provided a declaration showing that Blum's compounds "are unlikely to effectively inhibit an sEH because at least one of the substituents . . . is too bulky to inhibit the catalytic site of the sEH enzyme" (*id.* at 18; see also Reply Br. 12-14).

The issue presented is: Does the evidence of record support the Examiner's finding that practicing the method disclosed by Blum would inherently result in reducing hypertension by administering a therapeutically effective amount of an sEH inhibitor?

Findings of Fact

1. Blum discloses "substituted benzylamine derivatives which selectively bind to mammalian Neuropeptide Y1 (NPY1) receptors" (Blum, col. 1, ll. 11-13).

2. Blum discloses that "[c]ompounds that interact with NPY1 receptors and inhibit the activity of Neuropeptide Y at those receptors are useful in treating . . . hypertension" (*id.* at col. 3, ll. 19-24).

3. Blum discloses several exemplary compounds (*id.* at col. 1, l. 45 to col. 3, l. 15).

4. The Examiner finds that Blum's exemplary compounds meet the requirements of the structure recited in claims 46 and 48 (Ans. 4). Appellants do not dispute this finding (see Appeal Br. 16, n. 2).

5. Blum discloses that "[d]osage levels of the order of from about 0.1 mg to about 140 mg per kilogram of body weight per day are useful in the treatment of the above-indicated conditions" (*id.* at col. 10, ll. 47-49).

6. The instant Specification states that a "therapeutically effective amount of the compounds of the invention is employed in treatment. . . . An exemplary dose is from about 0.001 μM/kg to about 100 mg/kg body weight." (Spec. 27-28.)

7. Appellants have submitted a declaration under 37 C.F.R. § 1.132 by Bruce D. Hammock ("First Hammock Declaration," dated May 30, 2006).

8. Dr. Hammock declared:

> I disagree with the [Examiner's] contention that the compounds disclosed by [Blum] would function to significantly inhibit sEH (hereafter, "sEH") at physiologically relevant concentrations. (I put this qualification in since many otherwise inactive compounds are capable of inhibiting an enzyme's activity if present at concentrations beyond those that can be achieved *in vivo*.)

(First Hammock Declaration, ¶ 5.)

9. Dr. Hammock declared:

> My laboratory has now investigated the structure activity relationships ("SAR") of over 2000 compounds with regard to the ability of these compounds to inhibit human sEH. . . . As a result of these studies, I predict that the compounds disclosed by . . . Blum will not significantly inhibit human sEH at physiologically relevant concentrations.

(*Id.* at ¶ 6.)

10. Dr. Hammock addressed four of Blum's exemplary compounds, and declared that two of them would have "poor to no activity as an inhibitor

of sEH" (*id.* at ¶ 12) and that, for two others, "[t]here is a chance that this compound could be of mediocre activity" (*id.*).

Principles of Law

"It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art." *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985).

"[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

Analysis

Claims 46 and 48 are directed to a method of reducing hypertension (or blood pressure) by administering "a therapeutically effective amount of an inhibitor of soluble epoxide hydrolase" having a particular structure.

Blum discloses administering certain compounds to treat hypertension. Appellants do not dispute that Blum's compounds have the structure recited in the claims. The only issue, therefore, is whether Blum discloses administering "a therapeutically effective amount of an inhibitor of soluble epoxide hydrolase," as recited in the claims.

Blum discloses that its compounds can be administered at doses of up to 140 mg per kg body weight per day (FF 5). Appellants' Specification discloses that a therapeutically effective dose of an sEH inhibitor can require

up to 100 mg per kg body weight (FF 6). Appellants have provided evidence that some of the compounds disclosed by Blum can be predicted to be "mediocre" sEH inhibitors (FF 10).

The evidence of record therefore shows that Blum's compounds can be expected to have some sEH-inhibiting activity and that both Blum's method and the claimed method can be practiced using relatively high dosages. The evidence therefore supports a conclusion that Blum's compounds, administered at the dosages taught by Blum, would reasonably be expected to inhibit sEH and to reduce blood pressure, as required by the claims.

Appellants have not provided evidence to show that Blum's specific compounds, or other sEH inhibitors with mediocre activity, do not inhibit sEH when administered at the highest dosage disclosed by Blum. Dr. Hammock's statement that he did not expect Blum's compounds to "significantly inhibit sEH at physiologically relevant concentrations" (FF 9) does not outweigh the evidence supporting the Examiner's rejection: Dr. Hammock did not define what he considered "physiologically relevant concentrations" or otherwise relate those concentrations to the dosages taught by Blum, nor did he provide a reasoned explanation of why a dosage of 140 mg/kg/day of a "mediocre" inhibitor would not be expected to inhibit sEH and reduce blood pressure.

Conclusion of Law

A preponderance of the evidence of record supports the Examiner's finding that practicing the method disclosed by Blum would inherently result in reducing hypertension by administering a therapeutically effective amount of an sEH inhibitor.

SUMMARY

We affirm the rejection of claims 46 and 48 as anticipated by Blum.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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